REMARKS

Status of the Claims

Claims 1-118 are pending in the present application. Claims 2, 3, 11, 24, 30, 31, 32, 36, 37, 38, 41, 42, 46, 47, 48, 49, 50, 51, 52, 53, 54, 59, 60 and 69 are or have been amended so as to be dependent on claim 19 or claim 23 and should thus be included with the elected invention. As a result of these amendments, claims 6, 7, 8, 9, 12, 13, 14, 25, 26, 27, 66, 67 should also be included together with the elected invention [since these claims depend upon a claim that has been amended to be within the scope of the elected invention]. Claims 33, 34, 35, 63, 64, 65 should be rejoined with the elected invention upon allowance of the elected invention since these method of use claims are dependent on claim 19, 23 or on claim 63. Non-elected claims 1, 4, 5, 10, 15, 16, 17, 18, 20, 21, 28, 29, 39, 40, 43, 44, 45, 55, 56, 57, 58, 61, 62 have been cancelled without prejudice or disclaimer of the subject matter contained therein. The Examiner is respectfully requested to clarify why claim 70 is not within the scope of the elected invention. Claims 71-118 have been added to further define the claimed invention. Applicants preserve the right of filing a divisional application directed to the non-elected invention at a later stage.

Claims 97-103, 104, and 106-114 are the same as or similar

in scope to the claims of U.S. Patent 6,607,745 and U.S. Published Application 20040022847. Applicants have added these claims so as to preserve their rights in the event that the Examiner initiates an interference.

PTO 1449's

Applicants have submitted Information Disclosure Statements on October 11, 2002 and February 24, 2004. However, the Examiner has not returned initialed and dated PTO 1449's. The Examiner is respectfully requested to consider the references listed in the above-mentioned Information Disclosure Statements and to return the initialed and dated PTO 1449's to the undersigned.

Election/Restrictions

Restriction is required by the Examiner under 35 U.S.C. 121 and 372. The restriction is between Groups I-XIV as outlined on pages 2-3 of the prior Office Action. The Examiner further requires election of species with respect to the carbohydrates and various diseases treatable by the method claims. The requirement for restriction is again respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants' prior traversal is herein incorporated by reference.

In order to simplify the issues, Applicants have cancelled many of the non-elected claims, amended the dependent claims to be dependent on elected claims and amended the method of use claims as suggested by MPEP §821.04 entitled "Rejoinder." According to MPEP §821.04, if Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

With respect to Applicants' previous remarks that "all diseases listed are related to inflammation," the Examiner's attention is directed to the second paragraph on page 2 of the specification, which is reproduced as follows:

> The invention relates to a method of preventing and treating diseases and conditions of mammals associated with the adhesion, metastatic and coronary cascades comprising applying a composition of complex carbohydrates and essential oils topically, orally or mucosally on a repeated basis. The invention also encompasses a method of preventing and treating diseases and conditions associated with the adhesion, metastatic and coronary cascades comprising orally or mucosally applying complex carbohydrates as the sole active ingredient.

The Examiner should note that one embodiment of the invention relates to a method of preventing and treating diseases and conditions associated with the adhesion, metastatic and coronary cascades comprising orally or mucosally applying

complex carbohydrates as the sole active ingredient.

The present inventors were the first in any art to recognize that inhibiting the various cascades with complex carbohydrates prevents and treats a broad spectrum of diseases and conditions. In this regard, the Examiner's attention is further directed to the description in the second full paragraph on page 6 through the first full paragraph on page 8 of the specification, which explains the mechanism for the invention.

> The **Adhesion Cascade** was first described in the early 1990s. In a summary by Adams and Shaw (The Lancet, 343, Apr. 2, 1994) the adhesion cascade which is stimulated when trauma occurs is divided into four sequential steps of tethering, triggering, strong adhesion and motility. Tethering interactions are mediated by a family of three lectin-like carbohydrate-binding molecules (selectins). These interactions are strong enough to cause the leukocytes to roll along the blood vessel walls to the site of trauma instead of flowing freely through such vessels, but not strong enough to cause these leukocytes to slow down. The triggering response is stimulated by factors such as cytokines and mediated by adhesion molecules called integrins. Integrins, by themselves, do not bind well to epithelium. However, when activated, integrins promote strong adhesion of the leukocyte to the epithelial surface. Leukocytes bind to the epithelial cells via their receptor sites such as CD44, CD31, etc. During strong adhesion, the interaction of these integrins with their ligands on the surface of the leukocytes are responsible for cessation of movement and flattening of the leukocyte. Finally, a process involving VCAM-1 and LFA-1 and other such integrins allows leukocytes to pass between endothelial cell junctions and into the tissue that has been traumatized. Collection of leukocytes at the site of trauma produces inflammation which is then followed by pain or other sequelae.

The present invention is based upon the premise that complex carbohydrates, including but not limited to glycosaminoglycans, bind to the receptor sites on leukocytes blocking their ability to tether to the blood vessel walls thus inhibiting the motility and interrupting the Adhesion cascade.

The **metastatic cascade** is very similar to the adhesion cascade. It has been proposed that tumor cells of all types contain CD44 receptor sites on their surface. These CD44 receptor sites appear to be involved in metastasis functioning similar to the receptor sites on leukocytes - tethering the tumor cells to the blood vessel wall and providing the motility necessary for movement from one site to another in the mammalian body. Once again, it is the premise of the present invention that complex carbohydrates, including but not limited to glycosaminoglycans, bind to the receptor sites on tumor cells blocking their ability to tether to the blood vessel walls and inhibiting the motility which, in turn, interrupts the potential for metastasis.

A **Coronary cascade** has recently been described in the Harvard Health Letter (December 1999, pg. 4-5). This cascade leads to the development of heart disease and stroke by causing plaque formation in the blood vessels. The theory is based on the premise that there are stable and unstable plaques produced on blood vessel walls. Unstable plaques are "swarming with T cells and macrophages" causing inflammation and make these plaques unstable. The T cells are described as sending macrophages a signal to release a protein called tissue factor which "spills out and encounters circulating blood, attracting platelets and triggers formation of a clot that quickly blocks up the artery". **The compositions of the present invention are believed to inhibit the macrophages from infiltrating into the unstable plaques, thus preventing and treating heart disease and stroke.**

It is unexpected that complex carbohydrates of the present invention could be administered topically, orally or mucosally in low doses to inhibit the various cascades preventing and treating such a broad spectrum of diseases and conditions.

Thus, Applicants' invention is based on a common mechanism that impacts many different diseases.

Applicants further clarify the mechanism of the invention in the last paragraph on page 8 of the specification as follows:

> More specifically, this invention describes a mechanism by which **inflammation**, including diseases and conditions associated therewith, tumor growth, tumor metastasis and/or allergies and allergy-related diseases can be prevented or treated.

Thus, Applicants clearly have a basis for stating that the various diseases are linked since they "relate to inflammation." However, it should be noted that it was the present inventors whom found this linkage among the diseases.

Claim Objections

Claim 68 is objected to under 35 C.F.R. 1.75 as being of improper dependent form for failing to further limit the subject matter of a previous claim. In response, claim 68 has been cancelled. Thus, this objection is moot.

Claim Rejections - 35 USC §112

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66 and 68 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth on pages 6-7 of the Office Action. This rejection is respectfully traversed. Reconsideration and

withdrawal thereof are requested.

The Examiner alleges that the recitations "high and low molecular weight ranges" and "low purity" are indefinite because they are unclear relative terms and because "high" and "low" have an entirely subjective meaning. The Examiner is both factually and legally incorrect on each of these points.

More specifically, the phrase "low purity" is clearly defined by Applicants in the specification. For instance, the description beginning on page 14, line 15 and ending on page 15, line 14 of the specification is reproduced below as follows:

> **A significant advantage of this invention is that pharmaceutical grade complex carbohydrates are not required. The invention preferably uses cosmetic or food grade complex carbohydrates. Such complex carbohydrates can be obtained from any source as long as the source is not contaminated with undesirable adventitious agents (disease-producing viruses, bacteria, fungi, parasites, etc.). For instance, cosmetic grade hyaluronic acid which is of low purity (containing up to 5% impurities such as proteins, nucleic acids, teichoic acids and endotoxins)** costs approximately $2,000/Kg, whereas high purity pharmaceutical grade hyaluronic acid required for injection into mammals costs at least $100,000/Kg and contains less than 0.5% impurities. **Low purity complex carbohydrates such as mucopolysaccharides may be contaminated with up to 5% wt/vol proteins, 5% wt/vol nucleic acids, 1% wt/vol teichoic acids, 5% wt/vol lipids, fractions of hyaluronic acid <30,000 (defined as reactive by both Balazs in U.S. Pat. No. 4,141,973 and della Valle in U.S. Pat. No. 5,166,331), 5% wt/vol endotoxins and other small molecules. Preferably "low purity" means containing up to about 5% impurities, more preferably from about 0.6-5% impurities, still more preferably from about 1-5% impurities. They will cause reactions when injected into monkey eyes or joints of horses but will not**

cause reactions when applied to the skin of mammals or when delivered orally or mucosally to such mammals. Because the pharmaceutical compositions of this invention are applied topically, orally or mucosally, these contaminants produce no adverse reactions (e.g. irritation or blistering of skin). Additionally, if one must select and use only certain molecular weight ranges of hyaluronic acid or salts thereof, the cost would be prohibitive. In fact, the presence of multiple molecular weight fractions in compositions of the present invention is preferable for the efficacy.

Accordingly, contrary to the position taken by the Examiner, the term "low purity" is defined with particularity by Applicants in their specification. Well established law supports Applicants' position that Applicants may be their own lexicographer. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 21 U.S.P.Q.2d 1383 (Fed. Cir. 1992). Also, see new claim 72.

With respect to the phrase "high and low molecular weight ranges," the Examiner is again factually and legally incorrect on this point. More specifically, the terms "high" and "low" with respect to molecular weight are clearly defined by Applicants in the specification. For instance, the description on page 17, lines 11-17 of the specification is reproduced below as follows:

> It is a preferred embodiment of this invention that at least two molecular weight ranges of complex carbohydrates be included in the pharmaceutical composition. At least one should be from a **low molecular weight range {from 1000 to <50,000 (e.g. 49,000)} and the other one or more should be from a higher molecular weight range (from 100,000 to 500,000 or >1,000,000).**

Also see page 15, line 27 through page 16, line 9 of the specification as follows:

> All molecular weight ranges of complex carbohydrates are effective in formulations of this invention. For instance, hyaluronic acid with a molecular weight of <1,000, 1,000 to 30,000, 100,000 - 500,000, >1,000,000 or >4,000,000 have proven to be effective. **It has been found that complex carbohydrates, especially glycosaminoglycans with lower molecular weights (e.g. <50,000, preferably <30,000) act more quickly than those with high molecular weights (e.g. >1,000,000).** However, the high molecular weight glycosaminoglycans provide a longer-lasting effect. It is believed that the latter macromolecules are broken down by enzymes in the body to smaller molecules. Therefore, there is a longer release of the more active smaller molecules producing a longer period of efficacy. Therefore, the preferred formulation includes a mixture of low and high molecular weight complex carbohydrates.

Accordingly, Applicants have clearly defined "high" and "low" in the specification such that "low" molecular weights means <50,000 and "high" molecular weights means from 100,000 to 500,000 or >1,000,000.

The Examiner further rejects the phrase "are delivered in" in claim 66. This phrase has been amended to address the matters raised by the Examiner. The amendments to claim 66 are clearly non-narrowing in nature.

Claim 68 has been rejected as not further limiting claim 19. Thus, claim 68 has been cancelled rendering this rejection moot.

Finally, the recitation "comprises…0.005 to 50 mg/kg body weight" has been cancelled from independent claim 19.

Each of the rejections under 35 U.S.C. 112, second paragraph, has been discussed above. Based on the above-mentioned comments, the rejections under 35 U.S.C. 112, second paragraph should be withdrawn by the Examiner.

Claim Rejections - 35 U.S.C. §102

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66 and 68 are rejected by the Examiner under 35 U.S.C. 102(b) for the reasons set forth on pages 8-9 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Present Invention

A first embodiment of the present invention as recited in claim 19 relates to a composition which comprises at least one orally ingestable or mucosally absorbable complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans, and a carrier selected from the group consisting of a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable

capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A second embodiment of the present invention as recited in claim 22 relates to a composition which comprises, as an active ingredient, a pharmacologically effective amount of at least one orally ingestable or mucosally absorbable complex carbohydrate selected from the group consisting of a mixture of high and low molecular weight ranges of hyaluronic acid, and a carrier selected from the group consisting of a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A third embodiment of the present invention as recited in claim 23 relates to a composition which comprises as an active ingredient a pharmacologically effective amount of at least one orally ingestable or mucosally absorbable low purity complex carbohydrate selected from the group consisting of

oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, and a carrier selected from the group consisting of a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A fourth embodiment of the present invention as recited in claim 73 relates to an orally ingested or mucosally-absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises an effective amount of at least one complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans for treating inflammation, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally ingested or mucosally-absorbed pharmaceutical composition is selected from

the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A fifth embodiment of the present invention as recited in claim 92 relates to an orally ingested or mucosally absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises, as an active ingredient, a pharmacologically effective amount of at least one complex carbohydrate selected from the group consisting of a mixture of high and low molecular weight ranges of hyaluronic acid, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally or mucosally-administered pharmaceutical composition is selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet,

ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A sixth embodiment of the present invention as recited in claim 94 relates to an orally ingested or mucosally-absorbed pharmaceutical composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, which comprises as an active ingredient a pharmacologically effective amount of at least one complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, with the proviso that said composition does not contain an essential oil as an active ingredient, wherein said orally ingested or mucosally-absorbed pharmaceutical composition is selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement, with the proviso that when chondroitin sulfate is

used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

A seventh embodiment of the present invention as recited in claim 117 relates to a composition comprising at least one orally digestable or mucosally absorbable complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides, and glycosaminoglycans, wherein said at least one complex carbohydrate is mixed in a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, an ingestable tablet, a chewable tablet, a dissolvable tablet, and an ingestable nutritional supplement so that they contain at least 0.00005mg of the complex carbohydrate, with the proviso that when chondroitin sulfate is used as the sole glycosoaminoglycan, the carrier is not a capsule or an ingestable tablet.

The Examiner should further note that dependent claims 73-91 recite various members of the Markush Group set forth in independent claim 73.

U.S. Patent 4,303,676 to Balazs

U.S. Patent 4,303,676 to Balazs teaches a water-based, viscoelastic composition which is useful as the base for cosmetic compositions. See the abstract and col. 1, lines 59-62. The Balazs composition is to be used on the skin. See col. 3, lines 20-25 of the Balazs patent.

Distinctions Between the Present Invention and Balazs

The present invention is a composition selected from the group consisting of drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement. Clearly, there is no teaching of a composition [e.g. an orally or mucosally-delivered] as claimed. Indeed, Balazs expressly teaches away from the claimed [e.g. oral and/or mucosal composition] since the composition of Balazs is designed as a cosmetic for the skin.

More specifically, Balazs nowhere teaches or suggests drink, drink mix, food, candy, mouthwash, toothpaste, gargle, vaporizer, gum, lozenge, ingestable gel, ingestable foam, ingestable capsule, tablet, ingestable tablet, ingestable dissolvable tablet, suppository, and ingestable nutritional supplement as claimed. The preamble of the present invention

must be given patentable weight since it breathes life into the claim. To insure consideration of the preamble by the Examiner, the subject matter of the preamble has been incorporated into the body of each of independent claims 73, 92 and 94.

Accordingly, contrary to the position taken by the Examiner, there is no disclosure or suggestion of, for instance, a drink as claimed by the present inventors. There is no motivation to use the Balazs cosmetic composition as a drink nor is such a composition inherently a drink.

The Examiner states in the last paragraph on page 8 of the Office Action the following:

> It is noted that the composition is not designated as being for oral administration.

Accordingly, by the Examiner's own admission, the Balazs composition cannot anticipate the present invention.

However, the Examiner attempts to justify the anticipation rejection and further states in the last paragraph on page 8 of the Office Action the following:

> …the HPE composition disclosed by Balazs is in liquid form, and therefore clearly can be administered orally, and therefore can be considered a food or drink…Because Balasz's compositions can be administered orally, and because they are in the form of food and drink, as those terms are properly construed most broadly, a holding of anticipation is clearly required.

The Examiner's premise that the Balazs composition is not designated as being for oral administration is correct. The Examiner's conclusion that the Balazs cosmetic composition is a food or drink is both factually and legally in error.

More specifically, the Examiner's logic is that it must follow that any liquid can be administered orally since it is in liquid form, and therefore any liquid can be considered a food or drink. This is both patently false and not logical since many liquids will make one sick or are poisonous and cannot be considered food or drink simply because they are liquids.

Further, the Examiner's broad construction is not even consistent with the teachings of the Balazs patent, which is directed to cosmetic compositions and to a water-based composition used to make the cosmetic composition. There is simply no basis to state that such compositions are food or drink [or any of the other types of compositions as claimed].

Law of Inherency

To support a rejection based upon inherency, an Examiner must provide factual and technical grounds establishing that the inherent feature *necessarily* flows from the teachings of the prior art. See *Ex parte Levy* 17 USPQ2d 1461 (BOPAI 1990); see also *In re Oelrich*, 212 USPQ 323 (CCPA 1981) holding that inherency *must* flow as a necessary conclusion from the prior art, not simply a

possible one. The Examiner has failed to support his rejection consistent with applicable case law.

The Federal Circuit stated in In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999), that "to establish inherency, extrinsic evidence must make clear that the missing descriptive matter was necessarily present in the thing described in the reference, and would be so recognized by persons with ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a set of circumstances is not sufficient." In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999). Further, it has been held that the mere fact that a certain thing may result from a given set of circumstances is not sufficient, and occasional results are not inherent. MEHL/Biophile International v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999).

Further, the Examiner has not basis for restating or repackaging this rejection under 35 U.S.C. 103. That which is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under § 103. See *In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-57 (C.C.P.A. 1977).

Arguments based on inherent properties cannot stand when there is no supporting teaching in the prior art. *In re Spormann*, 363 F.2d 444,448, 150 U.S.P.Q. 449 (C.C.P.A. 1966).

Inherency and obviousness are distinct concepts. Thus, an applicant may in certain circumstances attack an obviousness rejection as improper if the Examiner indicates that specific features of the application, although not shown in the prior art, are inherent.

Since there is no evidence that the prior art teaches or suggests that the Balazs liquid cosmetic composition is a food or drink [or any of the other claimed materials], then Applicants respectfully submit that the rejection is not tenable. As such, Applicants respectfully request that the rejection be withdrawn because the Examiner has no basis for alleging that the claimed composition is inherent in the prior art.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of $55.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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